

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION**

**MDL NO. 1968**

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**THIS DOCUMENT RELATES TO ALL CASES**

**MASTER ANSWER OF DEFENDANTS  
ACTAVIS TOTOWA LLC, ACTAVIS INC., AND ACTAVIS ELIZABETH LLC**

Defendants Actavis Totowa LLC (“Actavis Totowa”), Actavis Inc. (“Actavis”), and Actavis Elizabeth LLC (“Actavis Elizabeth”) (“Defendants”), by and through counsel, state as follows for their Master Answer to the Master Consolidated Complaint for Individuals:

**I. INTRODUCTION**

1. The allegations in Paragraph 1 of Plaintiffs’ Master Consolidated Complaint require no response from Defendants. To the extent an answer is required, Defendants deny the allegations for want of knowledge and lack of information.

**II. PARTIES**

2. The allegations in Paragraph 2 of Plaintiffs’ Master Consolidated Complaint require no response from Defendants. To the extent an answer is required, Defendants deny the allegations for want of knowledge and lack of information.

3. Defendants admit that Actavis Totowa has its principal place of business in New Jersey and that, at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® under an Abbreviated New Drug Application (“ANDA”). Defendants deny the remaining allegations in Paragraph 3 of Plaintiffs’ Master Consolidated Complaint.

4. Defendants admit that Actavis Inc. is a Delaware corporation. Defendants deny the remaining allegations in Paragraph 4 of Plaintiffs’ Master Consolidated Complaint.

5. Defendants admit that Actavis Elizabeth is a Delaware limited liability company. Defendants deny the remaining allegations in Paragraph 5 of Plaintiffs' Master Consolidated Complaint, and specifically deny that Actavis Elizabeth designs, manufactures, markets, tests, promotes, sells, distributes, or has any other involvement with Digitek®.

6. Defendants admit that Mylan Inc. is a Pennsylvania corporation. Defendants deny the remaining allegations in Paragraph 6 of Plaintiffs' Master Consolidated Complaint.

7. Defendants admit that Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a West Virginia corporation with its principal place of business located in Morgantown, West Virginia. Defendants deny the remaining allegations in Paragraph 7 of Plaintiffs' Master Consolidated Complaint.

8. Defendants admit that Mylan Bertek Pharmaceuticals, Inc. ("Mylan Bertek") is a Texas corporation. Defendants deny the remaining allegations in Paragraph 8 of Plaintiffs' Master Consolidated Complaint.

9. Defendants admit that UDL Laboratories, Inc. ("UDL Labs") is an Illinois corporation. Defendants also admit that at all times relevant to the captioned matter, UDL Labs distributed Digitek® under a "UDL" label, but deny the remaining allegations in Paragraph 9 of Plaintiffs' Master Consolidated Complaint.

### **III. JURISDICTION AND VENUE**

10. Defendants admit that this Court has subject matter jurisdiction under 28 U.S.C. § 1322 for pre-trial purposes, only.

11. The allegations in Paragraph 11 of Plaintiffs' Master Consolidated Complaint require no response from Defendants. To the extent a response is required, Defendants admit that, per Pretrial Order #19, they have agreed – solely for the purpose of consolidated discovery and related pretrial proceedings – to waive their defense of improper venue in cases filed directly

into the MDL or into the United States District Court for the Southern District of West Virginia (“direct filed” cases). Defendants admit that for direct filed cases, the defense of improper venue is not waived and will be asserted on a case by case basis, as Defendants deem appropriate. To the extent the remaining jurisdictional allegations set forth in Paragraph 11 of the Master Complaint pertain to direct filed cases, Defendants deny the same.

#### **IV. FACTUAL ALLEGATIONS**

12. Defendants admit that Digitek<sup>®</sup> is a cardiac glycoside indicated for the treatment of heart failure and atrial fibrillation. Defendants deny the remaining allegations in Paragraph 12 of Plaintiffs’ Master Consolidated Complaint.

13. Defendants admit that Mylan Bertek distributed Digitek<sup>®</sup> from 1999 to 2005 and that Mylan Pharmaceuticals began distributing Digitek<sup>®</sup> under a “Bertek” label in 2005. Further, Defendants admit that UDL Labs began distributing Digitek<sup>®</sup> in 1999. Defendants deny the remaining allegations in Paragraph 13 of Plaintiffs’ Master Consolidated Complaint.

14. Defendants admit that Digitek<sup>®</sup> is indicated for the treatment of heart failure and atrial fibrillation, and that the FDA regulates the sale of Digitek<sup>®</sup> in the United States and approved the sale of 0.125 mg and 0.250 mg dosages. Defendants deny the remaining allegations in Paragraph 14 of Plaintiffs’ Master Consolidated Complaint.

15. Defendants admit the allegations in Paragraph 15 of Plaintiffs’ Master Consolidated Complaint.

16. Defendants admit that the FDA approved the sale of 0.125 mg and 0.250 mg dosages of Digitek<sup>®</sup>, but deny the remaining allegations in Paragraph 16 of Plaintiffs’ Master Consolidated Complaint.

17. Defendants admit that digoxin overdose and toxicity can cause serious injury and even death, but deny that any Plaintiff or Decedent exhibited such symptoms as a result of the

alleged ingestion of Digitek®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 17 of Plaintiffs' Master Consolidated Complaint, and therefore deny the same.

18. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa, formerly known as Amide Pharmaceutical, Inc., manufactured Digitek® at a Little Falls, New Jersey facility under an FDA-approved ANDA, but deny the remaining allegations in Paragraph 18 of Plaintiffs' Master Consolidated Complaint.

19. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 19 of Plaintiffs' Master Consolidated Complaint.

20. Defendants admit that the August 2006 letter is available on the FDA's website, but deny that the website address in Paragraph 20 of Plaintiffs' Master Consolidated Complaint is accurate.

21. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 21 of Plaintiffs' Master Consolidated Complaint.

22. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 22 of Plaintiffs' Master Consolidated Complaint.

23. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 23 of Plaintiffs' Master Consolidated Complaint.

24. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 24 of Plaintiffs' Master Consolidated Complaint.

25. Defendants deny the allegations in Paragraph 25 of Plaintiffs' Master Consolidated Complaint.

26. The FDA's Good Manufacturing Practice regulations speak for themselves and, on that basis, Defendants deny the allegations in Paragraph 26 of Plaintiffs' Master Consolidated Complaint.

27. Defendants admit the allegations in Paragraph 27 of Plaintiffs' Master Consolidated Complaint.

28. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 28 of Plaintiffs' Master Consolidated Complaint.

29. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 29 of Plaintiffs' Master Consolidated Complaint.

30. Defendants admit that the FDA issued an inspection report form to Actavis Totowa in August 2006. The document speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 30 of Plaintiffs' Master Consolidated Complaint.

31. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 31 of Plaintiffs' Master Consolidated Complaint.

32. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 32 of Plaintiffs' Master Consolidated Complaint.

33. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 33 of Plaintiffs' Master Consolidated Complaint.

34. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 34 of Plaintiffs' Master Consolidated Complaint, including subparagraphs (a) through (f).

35. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 35 of Plaintiffs' Master Consolidated Complaint.

36. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 36 of Plaintiffs' Master Consolidated Complaint.

37. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 37 of Plaintiffs' Master Consolidated Complaint.

38. Defendants admit the allegations in Paragraph 38 of Plaintiffs' Master Consolidated Complaint.

39. Defendants admit the allegations in Paragraph 39 of Plaintiffs' Master Consolidated Complaint.

40. Defendants deny the allegations in Paragraph 40 of Plaintiffs' Master Consolidated Complaint.

41. Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were subject only to those duties imposed by applicable law and deny any such duty was breached. Defendants deny the remaining allegations in Paragraph 41 of Plaintiffs' Master Consolidated Complaint, including subparagraphs (a) through (d).

42. Defendants deny the allegations in Paragraph 42 of Plaintiffs' Master Consolidated Complaint.

43. Defendants deny the allegations in Paragraph 43 of Plaintiffs' Master Consolidated Complaint, including subparagraphs (a) through (l).

44. Defendants deny the allegations in Paragraph 44 of Plaintiffs' Master Consolidated Complaint.

45. Defendants admit that Actavis Totowa agreed to stop commercial production and distribution of products manufactured at its facilities until it has demonstrated compliance with the FDA's current Good Manufacturing Practice regulations, but deny the remaining allegations in Paragraph 45 of Plaintiffs' Master Consolidated Complaint.

46. Defendants' publically available corporate documents and websites speak for themselves and, on that basis, Defendants deny the allegations in Paragraph 46 of Plaintiffs' Master Consolidated Complaint.

47. Defendants deny the allegations in Paragraph 47 of Plaintiffs' Master Consolidated Complaint.

48. Defendants deny the allegations in Paragraph 48 of Plaintiffs' Master Consolidated Complaint.

49. Defendants deny the allegations in Paragraph 49 of Plaintiffs' Master Consolidated Complaint.

50. Defendants deny the allegations in Paragraph 50 of Plaintiffs' Master Consolidated Complaint.

51. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek<sup>®</sup> under an FDA-approved ANDA, Mylan Pharmaceuticals distributed Digitek<sup>®</sup> under a "Bertek" label, and UDL Labs distributed Digitek<sup>®</sup> under a "UDL" label. Defendants deny the remaining allegations in Paragraph 51 of Plaintiffs' Master Consolidated Complaint.

52. Defendants admit that digoxin overdose and toxicity can cause serious injury and even death, but deny that any Plaintiff or Decedent exhibited such symptoms as a result of the alleged ingestion of Digitek<sup>®</sup>. Defendants deny the remaining allegations in Paragraph 52 of Plaintiffs' Master Consolidated Complaint.

53. Defendants deny the allegations in Paragraph 53 of Plaintiffs' Master Consolidated Complaint, and specifically deny that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

**V. CLAIMS FOR RELIEF**

**COUNT ONE:  
PRODUCT LIABILITY – FAILURE TO WARN AND INSTRUCT**

54. In response to Paragraph 54 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 53 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

55. Defendants admit that Mylan Bertek distributed Digitek<sup>®</sup> from 1999 to 2005 and that Mylan Pharmaceuticals began distributing Digitek<sup>®</sup> under a "Bertek" label in 2005. Further,



Defendants admit that UDL Labs began distributing Digitek<sup>®</sup> in 1999. The Digitek<sup>®</sup> label speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 55 of Plaintiffs' Master Consolidated Complaint.

56. Defendants admit that Digitek<sup>®</sup> tablets were expected to reach patients without a substantial change in their condition from the time they were sold. Defendants deny the remaining allegations in Paragraph 56 of Plaintiffs' Master Consolidated Complaint.

57. Defendants deny the allegations in Paragraph 57 of Plaintiffs' Master Consolidated Complaint.

58. Defendants deny the allegations in Paragraph 58 of Plaintiffs' Master Consolidated Complaint and specifically deny that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

59. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 59 of Plaintiffs' Master Consolidated Complaint, and therefore deny the same. Defendants deny that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Paragraph 59 of Plaintiffs' Master Consolidated Complaint.

60. Defendants deny the allegations in Paragraph 60 of Plaintiffs' Master Consolidated Complaint.

61. Defendants deny the allegations in Paragraph 61 of Plaintiffs' Master Consolidated Complaint.

62. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 of Plaintiffs' Master Consolidated Complaint, and therefore deny the same.

63. Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were

subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 63 of Plaintiffs' Master Consolidated Complaint.

64. Defendants state that, at all times, Plaintiffs received adequate information and warnings regarding the dose of digoxin in the recalled Digitek<sup>®</sup>. For lack of knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 64 of Plaintiffs' Master Consolidated Complaint, Defendants deny same.

65. Defendants deny the allegations in Paragraph 65 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 65 of Plaintiffs' Master Consolidated Complaint.

**COUNT TWO:**  
**PRODUCT LIABILITY – MANUFACTURING DEFECT**

66. In response to Paragraph 66 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 65 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

67. Defendants admit that Mylan Bertek distributed Digitek<sup>®</sup> from 1999 to 2005 and that Mylan Pharmaceuticals began distributing Digitek<sup>®</sup> under a "Bertek" label in 2005. Further, Defendants admit that UDL Labs began distributing Digitek<sup>®</sup> in 1999. The Digitek<sup>®</sup> label speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 67 of Plaintiffs' Master Consolidated Complaint.

68. Defendants admit that Digitek<sup>®</sup> tablets were expected to reach patients without a substantial change in their condition from the time they were sold. Defendants deny the

remaining allegations in Paragraph 68 of Plaintiffs' Master Consolidated Complaint, specifically denying that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

69. Defendants deny the allegations in Paragraph 69 of Plaintiffs' Master Consolidated Complaint, specifically denying that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

70. Defendants deny the allegations in Paragraph 70 of Plaintiffs' Master Consolidated Complaint, specifically denying that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

71. Defendants deny the allegations in Paragraph 71 of Plaintiffs' Master Consolidated Complaint, specifically denying that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

72. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 72 of Plaintiffs' Master Consolidated Complaint, and therefore deny the same. Defendants deny that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Paragraph 72 of Plaintiffs' Master Consolidated Complaint.

73. Defendants deny the allegations in Paragraph 73 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 73 of Plaintiffs' Master Consolidated Complaint.

**COUNT THREE:**  
**PRODUCT LIABILITY – DESIGN DEFECT**

74. In response to Paragraph 74 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 73 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

75. Defendants admit that Mylan Bertek distributed Digitek<sup>®</sup> from 1999 to 2005 and that Mylan Pharmaceuticals began distributing Digitek<sup>®</sup> under a “Bertek” label in 2005. Further, Defendants admit that UDL Labs began distributing Digitek<sup>®</sup> in 1999. The Digitek<sup>®</sup> label speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 75 of Plaintiffs’ Master Consolidated Complaint.

76. Defendants admit that Digitek<sup>®</sup> tablets were expected to reach patients without a substantial change in their condition from the time they were sold. Defendants deny the remaining allegations in Paragraph 76 of Plaintiffs’ Master Consolidated Complaint.

77. Defendants deny the allegations in Paragraph 77 of Plaintiffs’ Master Consolidated Complaint, specifically denying that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

78. Defendants deny the allegations in Paragraph 78 of Plaintiffs’ Master Consolidated Complaint, including subparagraphs (a) through (e), specifically denying that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

79. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 79 of Plaintiffs’ Master Consolidated Complaint, and therefore deny the same. Defendants deny that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Paragraph 79 of Plaintiffs’ Master Consolidated Complaint.

80. Defendants deny the allegations in Paragraph 80 of Plaintiffs’ Master Consolidated Complaint.

81. Defendants deny the allegations in Paragraph 81 of Plaintiffs’ Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the

injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 81 of Plaintiffs' Master Consolidated Complaint.

**COUNT FOUR:**  
**NEGLIGENCE**

82. In response to Paragraph 82 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 81 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

83. Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 83 of Plaintiffs' Master Consolidated Complaint.

84. Defendants deny the allegations in Paragraph 84 of Plaintiffs' Master Consolidated Complaint, including subparagraphs (a) through (i).

85. Defendants deny the allegations in Paragraph 85 of Plaintiffs' Master Consolidated Complaint.

86. Defendants deny the allegations in Paragraph 86 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Paragraph 86 of Plaintiffs' Master Consolidated Complaint.

87. Defendants deny the allegations in Paragraph 87 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 87 of Plaintiffs' Master Consolidated Complaint.

88. Defendants deny the allegations in Paragraph 88 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the

injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 88 of Plaintiffs' Master Consolidated Complaint.

**COUNT FIVE:**  
**NEGLIGENCE PER SE**

89. In response to Paragraph 89 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 88 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

90. Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 90 of Plaintiffs' Master Consolidated Complaint.

91. Defendants deny the allegations in Paragraph 91 of Plaintiffs' Master Consolidated Complaint.

92. The allegations in Paragraph 92 of Plaintiffs' Master Consolidated Complaint are legal conclusions for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 92 of Plaintiffs' Master Consolidated Complaint.

93. Defendants deny the allegations in Paragraph 93 of Plaintiffs' Master Consolidated Complaint.

94. Defendants deny the allegations in Paragraph 94 of Plaintiffs' Master Consolidated Complaint.

95. Defendants deny the allegations in Paragraph 95 of Plaintiffs' Master Consolidated Complaint.

96. Defendants deny the allegations in Paragraph 96 of Plaintiffs' Master Consolidated Complaint.

97. Defendants deny the allegations in Paragraph 97 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 97 of Plaintiffs' Master Consolidated Complaint.

**COUNT SIX:**  
**BREACH OF IMPLIED WARRANTY**

98. In response to Paragraph 98 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 97 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

99. The allegations in Paragraph 99 of Plaintiffs' Master Consolidated Complaint are legal conclusions for which no response is required. To the extent a response is required, Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 99 of Plaintiffs' Master Consolidated Complaint.

100. Defendants deny the allegations in Paragraph 100 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek<sup>®</sup>.

101. Defendants deny the allegations in Paragraph 101 of Plaintiffs' Master Consolidated Complaint.

102. Defendants deny the allegations in Paragraph 102 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek<sup>®</sup> and that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

103. Defendants deny the allegations in Paragraph 103 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek® and that Digitek® was the proximate cause of any alleged injuries and damages.

**COUNT SEVEN:**  
**BREACH OF EXPRESS WARRANTY**

104. In response to Paragraph 104 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 103 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

105. Defendants deny the allegations in Paragraph 105 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®.

106. Defendants deny the allegations in Paragraph 106 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®.

107. Defendants deny the allegations in Paragraph 107 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

108. Defendants deny the allegations in Paragraph 108 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®.

109. Defendants deny the allegations in Paragraph 109 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any warranties in favor of, or



representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®, that Digitek® was the proximate cause of the injuries and damages alleged, and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 109 of Plaintiffs' Master Consolidated Complaint.

**COUNT EIGHT:**  
**NEGLIGENT MISREPRESENTATION**

110. In response to Paragraph 110 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 109 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

111. Defendants deny the allegations in Paragraph 111 of Plaintiffs' Master Consolidated Complaint.

112. Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 112 of Plaintiffs' Master Consolidated Complaint.

113. Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 113 of Plaintiffs' Master Consolidated Complaint.

114. Defendants deny the allegations in Paragraph 114 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

115. Defendants deny the allegations in Paragraph 115 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs

and/or Decedents by Defendants regarding Digitek®.

116. Defendants deny the allegations in Paragraph 116 of Plaintiffs' Master Consolidated Complaint, specifically denying that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 116 of Plaintiffs' Master Consolidated Complaint.

117. Defendants deny the allegations in Paragraph 117 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek® and that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 117 of Plaintiffs' Master Consolidated Complaint.

**COUNT NINE:**  
**INTENTIONAL MISREPRESENTATION**

118. In response to Paragraph 118 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 117 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

119. Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 119 of Plaintiffs' Master Consolidated Complaint.

120. Defendants deny the allegations in Paragraph 120 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

121. Defendants deny the allegations in Paragraph 121 of Plaintiffs' Master Consolidated Complaint, including subparagraphs (a) through (d), specifically denying the

existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek<sup>®</sup> and that any Digitek<sup>®</sup> tablets ingested by Plaintiffs and/or Decedents were defective.

122. Defendants deny the allegations in Paragraph 122 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek<sup>®</sup>.

123. Defendants deny the allegations in Paragraph 123 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek<sup>®</sup>.

124. Defendants deny the allegations in Paragraph 124 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek<sup>®</sup> and that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Paragraph 124 of Plaintiffs' Master Consolidated Complaint.

125. Defendants deny the allegations in Paragraph 125 of Plaintiffs' Master Consolidated Complaint, specifically denying that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 125 of Plaintiffs' Master Consolidated Complaint.

126. Defendants deny the allegations in Paragraph 126 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 126 of Plaintiffs' Master Consolidated Complaint.

**COUNT TEN:**  
**FRAUD**

127. In response to Paragraph 127 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 126 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

128. Defendants deny the allegations in Paragraph 128 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents and their physicians by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

129. Defendants deny the allegations in Paragraph 129 of Plaintiffs' Master Consolidated Complaint, including subparagraphs (a) through (d), specifically denying the existence of any representations to Plaintiffs and/or Decedents and their physicians by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

130. Defendants admit that Actavis Totowa, Actavis, and Actavis Elizabeth were subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 130 of Plaintiffs' Master Consolidated Complaint.

131. Defendants deny the allegations in Paragraph 131 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

132. Defendants deny the allegations in Paragraph 132 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

133. Defendants deny the allegations in Paragraph 133 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents and their physicians by Defendants regarding Digitek®.

134. Defendants deny the allegations in Paragraph 134 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

135. Defendants deny the allegations in Paragraph 135 of Plaintiffs' Master Consolidated Complaint, specifically denying that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 135 of Plaintiffs' Master Consolidated Complaint.

136. Defendants deny the allegations in Paragraph 136 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 136 of Plaintiffs' Master Consolidated Complaint.

**COUNT ELEVEN:**  
**CONSTRUCTIVE FRAUD**

137. In response to Paragraph 137 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 136 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

138. Defendants deny the allegations in Paragraph 138 of Plaintiffs' Master Consolidated Complaint.

139. Defendants deny the allegations in Paragraph 139 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents and their physicians or providers by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

140. Defendants deny the allegations in Paragraph 140 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents and their physicians or providers by Defendants regarding Digitek®.

141. Defendants deny the allegations in Paragraph 141 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

142. Defendants deny the allegations in Paragraph 142 of Plaintiffs' Master Consolidated Complaint, specifically denying that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 142 of Plaintiffs' Master Consolidated Complaint.

143. Defendants deny the allegations in Paragraph 143 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 143 of Plaintiffs' Master Consolidated Complaint.

**COUNT TWELVE:**  
**VIOLATION OF WEST VIRGINIA CONSUMER CREDIT AND**  
**PROTECTION ACT (WEST VIRGINIA CODE § 46A-6-101, et seq.)**

144. In response to Paragraph 144 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 143 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

145. Defendants admit that Actavis Totowa manufactured Digitek® under an FDA-approved ANDA, Mylan Pharmaceuticals distributed Digitek® under a "Bertek" label, and UDL Laboratories distributed Digitek® under a "UDL" label. Defendants deny the remaining allegations in Paragraph 145 of Plaintiffs' Master Consolidated Complaint.

146. Defendants deny the allegations in Paragraph 146 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

147. Defendants deny the allegations in Paragraph 147 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

148. Defendants deny the allegations in Paragraph 148 of Plaintiffs' Master Consolidated Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

149. Defendants deny the allegations in Paragraph 149 of Plaintiffs' Master Consolidated Complaint.

150. Defendants deny the allegations in Paragraph 150 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 150 of Plaintiffs' Master Consolidated Complaint.

**COUNT THIRTEEN:**  
**VIOLATION OF APPLICABLE CONSUMER PROTECTION**  
**AND/OR UNFAIR TRADE PRACTICES STATUTES**

151. In response to Paragraph 151 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 150 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

152. The statement regarding state statutes in Paragraph 152 of Plaintiffs' Master Consolidated Complaint requires no response from Defendants. Defendants deny the remaining allegations in Paragraph 152 of Plaintiffs' Master Consolidated Complaint, specifically denying

the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

153. Defendants deny the allegations in Paragraph 153 of Plaintiffs' Master Consolidated Complaint, including subparagraphs (a) through (yy).

154. Defendants deny the allegations in Paragraph 154 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 154 of Plaintiffs' Master Consolidated Complaint.

**COUNT FOURTEEN:  
WRONGFUL DEATH**

155. In response to Paragraph 155 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 154 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

156. Defendants deny the allegations in Paragraph 156 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 156 of Plaintiffs' Master Consolidated Complaint.

157. Defendants deny the allegations in Paragraph 157 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 157 of Plaintiffs' Master Consolidated Complaint.

158. The allegations in Paragraph 158 of Plaintiffs' Master Consolidated Complaint require no response from Defendants. To the extent an answer is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 158 of Plaintiffs' Master Consolidated Complaint, and therefore deny the same.



159. Defendants deny the allegations in Paragraph 159 of Plaintiffs' Master Consolidated Complaint, specifically denying that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 159 of Plaintiffs' Master Consolidated Complaint.

**COUNT FIFTEEN:  
SURVIVAL ACTION**

160. In response to Paragraph 160 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 159 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

161. Defendants deny the allegations in Paragraph 161 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Paragraph 161 of Plaintiffs' Master Consolidated Complaint.

162. The allegations in Paragraph 162 of Plaintiffs' Master Consolidated Complaint require no response from Defendants. To the extent an answer is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 162 of Plaintiffs' Master Consolidated Complaint, and therefore deny the same.

163. Defendants deny the allegations in Paragraph 163 of Plaintiffs' Master Consolidated Complaint, specifically denying that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 163 of Plaintiffs' Master Consolidated Complaint.

**COUNT SIXTEEN:  
MEDICAL MONITORING**

164. In response to Paragraph 164 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 163 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

165. Defendants deny the allegations in Paragraph 165 of Plaintiffs' Master Consolidated Complaint.

166. Defendants deny the allegations in Paragraph 166 of Plaintiffs' Master Consolidated Complaint.

167. Defendants deny the allegations in Paragraph 167 of Plaintiffs' Master Consolidated Complaint.

168. Defendants deny the allegations in Paragraph 168 of Plaintiffs' Master Consolidated Complaint.

**COUNT SEVENTEEN:  
UNJUST ENRICHMENT**

169. In response to Paragraph 169 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 168 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

170. Defendants deny the allegations in Paragraph 170 of Plaintiffs' Master Consolidated Complaint.

171. Defendants deny the allegations in Paragraph 171 of Plaintiffs' Master Consolidated Complaint.

172. Defendants deny the allegations in Paragraph 172 of Plaintiffs' Master Consolidated Complaint.

173. Defendants deny the allegations in Paragraph 173 of Plaintiffs' Master Consolidated Complaint, specifically denying that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 173 of Plaintiffs' Master Consolidated Complaint.

**COUNT EIGHTEEN:  
MEDICARE SECONDARY PAYER ACT**

174. In response to Paragraph 174 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 173 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

175. Paragraph 175 of Plaintiffs' Master Consolidated Complaint contains no allegations against Defendants. To the extent this paragraph is deemed to contain allegations against Defendants, they are denied.

**COUNT NINETEEN:  
LOSS OF CONSORTIUM**

176. In response to Paragraph 176 of Plaintiffs' Master Consolidated Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 175 of Plaintiffs' Master Consolidated Complaint as if fully set forth herein.

177. Defendants deny the allegations in Paragraph 177 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Paragraph 177 of Plaintiffs' Master Consolidated Complaint.

178. Defendants deny the allegations in Paragraph 178 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Paragraph 178 of Plaintiffs' Master Consolidated Complaint.

179. Defendants deny the allegations in Paragraph 179 of Plaintiffs' Master Consolidated Complaint.

180. Defendants deny the allegations in Paragraph 180 of Plaintiffs' Master Consolidated Complaint.

181. Defendants deny the allegations in Paragraph 181 of Plaintiffs' Master Consolidated Complaint.

182. Defendants deny the allegations in Paragraph 182 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged and that Plaintiffs and/or Decedents are entitled to the relief requested in Paragraph 182 of Plaintiffs' Master Consolidated Complaint.

**ANSWER TO PRAYER FOR RELIEF**

183. Defendants deny any and all allegations in Plaintiffs' Master Consolidated Complaint not expressly admitted, including any and all allegations set forth in the prayer for relief in the unnumbered paragraph following Paragraph 182 of Plaintiffs' Master Consolidated Complaint, specifically denying that Digitek<sup>®</sup> was the proximate cause of the injuries and damages alleged in Plaintiffs' Master Consolidated Complaint. Defendants also deny that Plaintiffs and/or Decedents are entitled to the relief requested in the prayer for relief set forth in the unnumbered paragraph following Paragraph 182 of Plaintiffs' Master Consolidated Complaint. Defendants specifically controvert the prayer for relief in the unnumbered paragraph following Paragraph 182 of Plaintiffs' Master Consolidated Complaint and request judgment in their favor, including costs and attorneys' fees.

Defendants demand a jury trial on all issues so triable.

**AFFIRMATIVE DEFENSES**

In further response to Plaintiffs' Master Consolidated Complaint, Defendants assert the following additional defenses:

**FIRST AFFIRMATE DEFENSE**

Plaintiffs' Master Consolidated Complaint fails to state a claim upon which relief can be granted as to some or all of Plaintiffs' claims.

**SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the applicable statute of limitations, statute of repose, and/or the equitable doctrines of laches and estoppel.

**THIRD AFFIRMATIVE DEFENSE**

Plaintiffs lack standing to assert claims under the law of a state in which they do not reside, or in which they did not purchase Digitek®.

**FOURTH AFFIRMATIVE DEFENSE**

The Court lacks personal jurisdiction over Defendants Actavis Inc. and Actavis-Elizabeth, L.L.C.

**FIFTH AFFIRMATIVE DEFENSE**

For any individual case that is not governed by the service provisions of Pretrial Order #16, Defendants reserve the defenses of insufficient process and insufficient service of process.

**SIXTH AFFIRMATIVE DEFENSE**

Venue is improper in the Southern District of West Virginia.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs lack standing to pursue their claims and/or seek the requested relief.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver.

**NINTH AFFIRMATIVE DEFENSE**

Plaintiffs and/or Decedents are responsible in whole or in part for any injuries suffered as a result of their contributory negligence, comparative negligence, or assumption of the risk.

**TENTH AFFIRMATIVE DEFENSE**

Some or all of Plaintiffs' claims are barred because Plaintiffs' and/or Decedents' alleged injuries and damages were actually or proximately caused, in whole or in part, by the intervening, superseding, or illegal conduct of Plaintiffs and/or Decedents, independent third

parties, or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, or independent of or far removed from Defendants' conduct or control.

**ELEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' and/or Decedents' alleged injuries and damages, if any, have been caused by factors unrelated to the product, including, but not limited to, preexisting medical, genetic and/or environmental conditions, diseases, illnesses, accidents or idiosyncratic or idiopathic reactions. Defendants have no control over such factors, and such factors were not due to, or caused by, any fault, lack of care, negligence or breach on Defendants' part.

**TWELFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred to the extent that any injuries were caused by a misuse, abuse, alteration, and/or failure to properly maintain or care for the subject product by persons other than Defendants.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the "state of the art" and "state of scientific knowledge" defenses.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Defendants are expressly and/or impliedly preempted by federal law, including, but not limited to, Plaintiffs' failure to warn claims. Plaintiffs' failure to warn claims are preempted under the Supremacy Clause of the United States Constitution by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), and regulations promulgated thereunder, including, but not limited to, 21 C.F.R. 314.150, and by the purposes and objectives of the FDCA and the Food and Drug Administration's implementing regulations,

and the specific determinations made by the Food and Drug Administration specifying the language that should be used in the labeling accompanying generic pharmaceutical products.

**FIFTEENTH AFFIRMATIVE DEFENSE**

All or part of Plaintiffs' claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Defendants and all their activities with respect to the subject product have been and are conducted under the supervision of the FDA.

**SIXTEENTH AFFIRMATIVE DEFENSE**

Defendants did not make nor did they breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between Plaintiffs and/or Decedents and Defendants, and/or by the failure of Plaintiffs and/or Decedents to give Defendants timely notice of the alleged breach of warranty. Defendants further specifically plead as to any breach of warranty claim all separate defenses under the Uniform Commercial Code, as enacted in the State of West Virginia and any other state whose law is deemed to apply in this case.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by comments *j* and *k* to Section 402A of the Restatement (Second) of Torts.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' product liability claims are barred because the benefits of the product outweighed its risks.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product at issue was at all times properly prepared, packaged, and distributed, and was not defective or unreasonably dangerous.

**TWENTIETH AFFIRAMTIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because Defendants acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of their product.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and



proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent. Defendants also invoke any similar or analogous provisions in individual state Constitutions, statutes, or common law to the extent the law of a particular state is controlling in any given case in this MDL.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claim for punitive damages is subject to the limitations and requirements of the state in which the claim arose.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

Punitive damages are inappropriate to serve deterrence objectives because those will be fully served by past and future liability for any compensatory damages for the same conduct at issue in this case.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' Master Consolidated Complaint fails to state sufficient facts under any theory or cause of action which would justify imposition of punitive or exemplary damages under any applicable law.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' Master Consolidated Complaint fails to allege facts from which it can reasonably be inferred that Defendants acted with reckless indifference to or conscious disregard for the safety of others sufficient to warrant punitive damages.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

The imposition of damages against Defendants violates their rights to due process under the Fifth and Fourteenth Amendments to the Constitution of the United States, as well as Article III, Section 10 of the Constitution of West Virginia and any other provisions of any other state whose law is deemed to apply in this case.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Defendants are entitled to a set-off for all amounts paid, payable by, or available from collateral sources, including write-offs/write-downs in charges.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by their failure to comply with conditions precedent to their right to recover.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Defendants are entitled to, and claim the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in West Virginia and any other state whose law is deemed to apply in this case.

**THIRTIETH AFFIRMATIVE DEFENSE**

The claims asserted in Plaintiffs' Master Consolidated Complaint are barred, in whole or in part, because they did not incur any ascertainable loss as a result of Defendants' conduct.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

The claims asserted in Plaintiffs' Master Consolidated Complaint are barred, in whole or in part, because the labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

Any product supplied by Defendants and sold in the normal stream of commerce was reasonably safe for its intended use and was not defective in any manner.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

If Plaintiffs and/or Decedents were exposed to any product manufactured, produced, sold, or supplied by Defendants, which is specifically denied, said exposure was *de minimis* and insufficient as a matter of law to establish with a reasonable degree or probability that the product at issue caused Plaintiffs' and/or Decedents' injuries.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

The damages recoverable by Plaintiffs, if any, must be reduced by any amount of damages legally caused by Plaintiffs' failure to mitigate such damages in whole or in part.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

Digitek<sup>®</sup>, if in fact ingested by Plaintiffs and/or Decedents, did not cause or contribute to any alleged injuries.

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

Digitek<sup>®</sup> was not unreasonably dangerous in formulation or composition at the time it left Defendants' control as it did not deviate in any way from Defendants' and the FDA's specifications.

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

Some or all of Plaintiffs' claims are barred by reason of spoliation of evidence.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims should be dismissed on *forum non conveniens* grounds.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the learned intermediary doctrine.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims under the West Virginia Consumer Credit and Protection Act are barred by Plaintiffs' failure to comply with the notice requirements under West Virginia Code § 46A-6-106(b).

**FORTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs have failed to allege their state-by-state statutory "unfair competition or unfair or deceptive acts or practices" claims with any particularity and thus, Defendants reserve the right to assert any and all defenses to those claims, jurisdictional or otherwise, that may apply under the applicable state law.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs have failed to state facts sufficient to constitute a cause of action under any consumer protection and/or unfair trade practices statutes.


**FORTY-FIFTH AFFIRMATIVE DEFENSE**

Defendants hereby reserve the right to amend their answer to assert any other defenses, separate or otherwise, that may become available during discovery proceedings in this case.

**WHEREFORE**, having fully answered, Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC respectfully request that this Court enter an Order dismissing Plaintiffs' Master Consolidated Complaint with prejudice at Plaintiffs' costs and granting the Defendants such other relief as it deems just and equitable.

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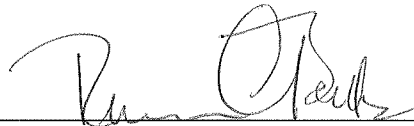
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*Attorneys for Defendants  
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**CERTIFICATE OF SERVICE**

I hereby certify that on April 20, 2009, I electronically filed the foregoing "Master Answer of Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

A handwritten signature in black ink, appearing to read "Rebecca A. Betts", is written over a horizontal line.

REBECCA A. BETTS (WVSB # 329)

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